Louisiana Medicaid
Immune Globulin (Human) Criteria

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for the use of immune globulin (human) agents.

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings**, and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria for All Diagnoses

- The requested medication is being used for a medically accepted indication as defined using the following sources and source(s) are **stated on the request**:
    - Food and Drug Administration (FDA); **OR**
    - Micromedex; **OR**
    - American Hospital Formulary Service (AHFS); **OR**
    - Drug-specific prescribing information (PI); **OR**
    - Disease state specific standard of care guidelines; **AND**
- For a non-preferred agent, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred agent, previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
    - The recipient is established on the medication with positive clinical outcomes; **AND**
- The recipient is within the age parameters defined by the drug-specific prescribing information**; AND**
- The diagnosis for which the medication is requested has been confirmed by a specialist [Name of specialist must be **stated on the request**]**; AND**
- The recipient has tried and failed, or has a documented medical reason for not using, all other standard of care therapies as defined per recognized guidelines [Dates and medications must be **stated on the request**]; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**

- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Additional diagnosis-specific criteria

Primary immunodeficiency*

- By submitting the authorization request, the prescriber attests to the following:
  - The recipient's IgG level is below normal level for indication**; AND**
  - The recipient has clinically significant deficiency of humoral immunity as evidenced by **ONE** of the following:
    - Inability to produce an adequate immunologic response to specific antigens; **OR**
    - History of recurrent infections despite prophylactic antibiotics; **AND**
  - The requested dose is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature.

* Primary Immunodeficiency includes the following: Congenital agammaglobulinemia; Hypogammaglobulinemia (Common Variable Immunodeficiency, CVID); Severe combined immunodeficiency (SCID); Wiskott-Aldrich syndrome; X-linked agammaglobulinemia or Bruton's agammaglobulinemia; Hypergammaglobulinemia; X-linked Hyper IgM syndrome.

Duration of approval: 6 months

Idiopathic Thrombocytopenic Purpura (acute or chronic)

- By submitting the authorization request, the prescriber attests that **ONE** of the following is true:
  - For recipients with a diagnosis of acute idiopathic thrombocytopenic purpura:
    - The recipient's condition is acute (defined as active bleeding, urgent invasive procedure, to defer splenectomy, platelet counts < 20,000/ul at risk for intra-cerebral hemorrhage or has life threatening bleeding); **AND**
    - The requested dose does not exceed 1g/kg daily for up to 2 days, or 400mg/kg daily for 5 days; **OR**
  - For recipients with a diagnosis of chronic idiopathic thrombocytopenic purpura:
    - The duration of illness is greater than 6 months (definition of chronic idiopathic thrombocytopenic purpura); **AND**
    - The recipient has a documented trial and failure of corticosteroids and splenectomy; **OR**
    - The recipient has a documented medical reason why they are not able to use corticosteroids; **OR**
    - The recipient is at high risk for post-splenectomy sepsis; **AND**
    - The requested dose does not exceed 1g/kg daily for up to 2 days, or 400mg/kg daily for 5 days.

Duration of approval: Up to 5 days

Kawasaki Disease

- By submitting the authorization request, the prescriber attests that the following statements are true:
  - The requested agent is being given with high dose aspirin; **AND**
  - The requested dose does not exceed a single 2g/kg dose or a dose of 400mg/kg for five consecutive days.

Duration of approval: Up to 5 days

Chronic B-cell Lymphocytic Leukemia

- The recipient's IgG level is < 500mg/dL and this is **stated on the request**; **AND**
- By submitting the authorization request, the prescriber attests that the following statements are true:
  - The recipient has history of severe bacterial infections; **AND**
  - The requested dose does not exceed 400mg/kg every 3-4 weeks.

Duration of approval: 3 months

Bone Marrow Transplantation

- The recipient IgG level is <400mg/dL and this is **stated on the request**; **AND**
- By submitting the authorization request, the prescriber attests that the following statements are true:
  - The recipient has had a bone marrow transplant within the last 100 days; **AND**
  - The requested dose does not exceed 500mg/kg/wk for the first 100 days post-transplant.

Duration of approval: 3 months

Pediatric HIV

- The recipient has a diagnosis of HIV and this is **stated on the request**; **AND**
- The recipient is < 13 years of age; **AND**
- The recipient's IgG level is **stated on the request; AND**
- By submitting the request, the prescriber attests to the following:
  - If the recipient's IgG level is ≥ 400 mg/dL, there is significant deficiency of humoral immunity as evidenced by **ONE** of the following:
    - An inability to produce an adequate immunologic response to specific antigens; **OR**
    - A history of recurrent bacterial infections despite prophylactic antibiotics; **AND**
  - The requested dose does not exceed 400mg/kg/dose every 14 days.

Duration of approval: 3 months

Multifocal motor neuropathy (MMN)

- By submitting the authorization request, the prescriber attests that the following statements are true:
    - The duration of symptoms has been at least one month with disability; **AND**
    - Nerve conduction studies were completed to rule out other possible conditions, and confirms the diagnosis of MMN; **AND**
    - The requested dose does not exceed 2g/kg/month.

Duration of approval: 3 months

Chronic inflammatory demyelinating polyneuropathy (CIDP)

- By submitting the authorization request, the prescriber attests that the following statements are true:
    - The duration of symptoms has been at least 2 months with disability; **AND**
    - Nerve conduction studies or a nerve biopsy were completed in order to rule out other possible conditions, and confirms the diagnosis of CIDP; **AND**
    - **ONE** of the following:
        - The recipient has tried and failed, or has a medical reason for not using, corticosteroids; OR
        - The recipient has severe and fulminant CIDP; **AND**
    - The requested dose is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature.

Duration of approval: 3 months

Guillain-Barre syndrome

- By submitting the authorization request, the prescriber attests that the following statements are true:
    - The recipient has severe disease with the inability to walk without aid; **AND**
    - The onset of symptoms has occurred within the last 4 weeks; **AND**
    - The requested dose does not exceed 2g/kg/month.

Duration of approval: 3 months

If criteria is met, the request will be approved for the duration listed above. If the criteria is not met, the request is referred to a clinical reviewer for medical necessity review. The clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.

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